416.195 A request to review.

416.200 Application of the payment adjustment.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 47 FR 34094, Aug. 5, 1982, unless otherwise noted.

Subpart A—General Provisions and Definitions

§416.1 Basis and scope.

- (a) Statutory basis. (1) Section 1832(a)(2)(F)(i) of the Act provides for Medicare Part B coverage of facility services furnished in connection with surgical procedures specified by the Secretary under section 1833(i)(1) of the Act.
- (2) Section 1833(i)(1)(A) of the Act requires the Secretary to specify the surgical procedures that can be performed safely on an ambulatory basis in an ambulatory surgical center, or a hospital outpatient department.
- (3) Section 1833(i) (2)(A) and (3) specify the amounts to be paid for facility services furnished in connection with the specified surgical procedures when they are performed, respectively, in an ASC, or in a hospital outpatient department.
 - (b) Scope. This part sets forth-
- (1) The conditions that an ASC must meet in order to participate in the Medicare program;
- (2) The scope of covered services; and (3) The conditions for Medicare payment for facility services.

[56 FR 8843, Mar. 1, 1991; 56 FR 23022, May 20, 1991]

§416.2 Definitions.

As used in this part:

Ambulatory surgical center or ASC means any distinct entity that operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization, has an agreement with CMS to participate in Medicare as an ASC, and meets the conditions set forth in subparts B and C of this part.

ASC services means facility services that are furnished in an ASC.

Covered surgical procedures means those surgical and other medical procedures that meet the criteria specified

in $\S416.65$ and are published by CMS in the FEDERAL REGISTER.

Facility services means services that are furnished in connection with covered surgical procedures performed in an ASC, or in a hospital on an outpatient basis.

[56 FR 8843, Mar. 1, 1991; 56 FR 23022, May 20, 1991]

Subpart B—General Conditions and Requirements

§416.25 Basic requirements.

Participation as an ASC is limited to facilities that—

- (a) Meet the definition in §416.2; and
- (b) Have in effect an agreement obtained in accordance with this subpart.

[56 FR 8843, Mar. 1, 1991]

§416.26 Qualifying for an agreement.

- (a) Deemed compliance. CMS may deem an ASC to be in compliance with any or all of the conditions set forth in subpart C of this part if—
- (1) The ASC is accredited by a national accrediting body, or licensed by a State agency, that CMS determines provides reasonable assurance that the conditions are met;
- (2) In the case of deemed status through accreditation by a national accrediting body, where State law requires licensure, the ASC complies with State licensure requirements; and
- (3) The ASC authorizes the release to CMS, of the findings of the accreditation survey.
- (b) Survey of ASCs. (1) Unless CMS deems the ASC to be in compliance with the conditions set forth in subpart C of this part, the State survey agency must survey the facility to ascertain compliance with those conditions, and report its findings to CMS.
- (2) CMS surveys deemed ASCs on a sample basis as part of CMS's validation process.
- (c) Acceptance of the ASC as qualified to furnish ambulatory surgical services. If CMS determines, after reviewing the survey agency recommendation and other evidence relating to the qualification of the ASC, that the facility meets the requirements of this part, it sends to the ASC—